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Does Canada's Foreign Trade Policy Give Innovating Canadian Firms a Competitive Edge Internationally?

Olena Ivus

Marta Paczos, *National Institute of Economic and Social Research*

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67 Erb Street West
Waterloo, ON, Canada N2L 6C2
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About the Authors

Olena Ivus joined CIGI's Global Economy Program in April 2016, focusing on the innovation and trade research theme. Her research explores the interface between Canada's domestic innovation and international trade.

Olena is associate professor of business economics at Queen's University's Smith School of Business in Kingston, Ontario. Prior to joining Queen's, she was assistant professor at the University of Prince Edward Island and attended as a visiting researcher at the Institute of Economic Research at Hitotsubashi University in Japan.

Olena holds a Ph.D. in economics from the University of Calgary.

Marta Paczos is an economist at the National Institute of Economic and Social Research in London and a research economist at the Economic Statistics Centre of Excellence.

About the Global Economy Program

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Acronyms and Abbreviations

CIPO	Canadian Intellectual Property Office
CUSMA	Canada-United States-Mexico Agreement
CETA	Comprehensive Economic and Trade Agreement
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
CSP	Certificates of Supplemental Protection
DRMS	digital rights management schemes
GATT	General Agreement on Tariffs and Trade
GIs	geographical indications
IP	intellectual property
IPRs	intellectual property rights
ISP	internet service provider
MFN	most favoured nation
NAFTA	North American Free Trade Agreement
PM(NOC)	Patented Medicines (Notice of Compliance)
PTA	patent term adjustment
PTR	patent term restoration
RMI	rights management information
RTAs	regional trade agreements
SPC	Supplementary Protection Certificate
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TPP	Trans-Pacific Partnership
TPMs	technological protection measures
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive Summary

In recent years, Canada has adopted the Comprehensive Economic and Trade Agreement (CETA), the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the Canada-United States-Mexico Agreement (CUSMA).

Like other modern international trade agreements, CETA, the CPTPP and the CUSMA include protections for innovators' profits and technologies in the form of intellectual property rights (IPRs) regulations. These trade agreements will have a first-order impact on the volume and composition of trade in goods and innovation with sensitive intellectual property (IP) in Canada, as well as having an impact on global welfare distribution. But is Canada's membership in these agreements good for Canadian firms looking to compete globally?

Modern international trade agreements include IPRs because they facilitate trade, including by encouraging exports (especially of new product varieties) and protecting the profit potential of otherwise imitable innovations abroad. In exchange for establishing stronger IPRs, foreign markets gain greater access to new technologies. With an increased number of countries involved in global trade, the world's economies have grown more interconnected, and the need for international coordination of IPRs has intensified.

The number of trade agreements that include IP clauses has greatly increased over the past few decades. The IP provisions in regional trade agreements (RTAs) supplement the IP rights and protections established by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and provide for still greater IP protections. Such "TRIPS-plus provisions" are spread beyond the agreements' members and serve to ensure that IPRs and protections only grow stronger across the globe. IP obligations in international trade agreements limit the freedom to use IP policy to promote national interests, but are also counterbalanced by several "flexibilities," including the right to establish local exhaustion policies.

With Canada's adoption of CETA, the CPTPP and the CUSMA comes a commitment to newer, more stringent IPRs. For these commitments

to benefit Canadian businesses, they must be coupled with efforts by the Government of Canada to build and sustain a climate supportive of innovation. This means reducing the costs of obtaining IP protection in Canada. Further, in areas where its trade agreements grant latitude (for example, patent exhaustion policy), Canada should establish national IPR policies that serve the best interests of Canadian stakeholders.

Introduction

The last three decades have seen a large increase in the number of bilateral and regional trade agreements that include IP provisions. The United States, in particular, has always closely guarded the interests of its IP producers, and worked untiringly to establish strong standards of IPRs and enforcement mechanisms across the globe, often imposing them as a precondition for increased access to US markets. Starting in the early 1990s, the North American Free Trade Agreement (NAFTA) was the first RTA to include a comprehensive chapter on IP. NAFTA formed the underpinnings for what became TRIPS, the most comprehensive multilateral agreement on IP to date. Since adopting TRIPS in 1994, the United States has gone on to negotiate several bilateral and regional-multilateral trade agreements that provide for still greater IP protections. Known as TRIPS-plus provisions, they supplement the IP rights and protections established by TRIPS.

Compared to the United States' tough approach right out of the gate, Canada's IP protection efforts after TRIPS were stunted. Twenty-five years later, however, Canada is party to three recently ratified mega-regional trade deals (CETA, the CPTPP and the CUSMA) that establish a broad set of IP protection rules and obligations above and beyond TRIPS standards. Have the increased IP protections been welfare enhancing for Canadians? Do they encourage domestic innovation and help homegrown innovating firms compete internationally? Or might these policies instead limit Canadian firms' access to innovative products and technologies, create barriers for innovation and fall short in protecting the rights of Canadian IP owners at home and abroad?

This paper begins with a review of the IP protections instituted through recent trade deals involving Canada. It discusses the nature and scope of Canada's IP obligations under CETA, the CPTPP and the CUSMA and explains how these obligations fit within the current Canadian legal framework. The changes in the standards of IPRs under these agreements will have a first-order impact on the volume and composition of trade in IP-sensitive goods, innovation and global welfare distribution and so deserve thorough debate.¹ The paper then proceeds with a broader discussion of the reasons to include IP provisions in international trade agreements and the rationale for international coordination of the IPRs policy. Next, the paper discusses how IP provisions in trade agreements limit the freedom to use IP policy to promote national interests, while acknowledging that the various IP obligations are counterbalanced by several flexibilities, including the right to establish local exhaustion policies. The paper concludes with policy recommendations.

IP Provisions in Canadian RTAs

The three RTAs that Canada has recently negotiated — CETA, the CPTPP and the CUSMA — are complex and lengthy, and a full treatment of their various legal implications is beyond the scope of this paper. A general understanding of their overall structure is helpful in order to put the relevant discussion into context.

CETA is “a progressive trade agreement”² between Canada and the European Union. It came into force provisionally on September 21, 2017. CETA's IP provisions are found at chapter 20 of the agreement.

The CPTPP was signed on March 8, 2018, by 11 countries: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. The CPTPP is also known as TPP11.

The CPTPP member countries were the original signatories to the Trans-Pacific Partnership (TPP) agreement, which, together with the United States, was signed on February 4, 2016. The United States withdrew from the agreement a year later, preventing the TPP from coming into force. Following the United States' withdrawal, the other 11 signatories agreed in May 2017 to revive and renegotiate the TPP, leading to the CPTPP. The CPTPP incorporates, by reference, most of the provisions from the TPP but suspends certain provisions in areas of patent and copyright protection, internet service provider (ISP) liability and IPRs enforcement that were demanded only by the United States.³ The CPTPP came into force on December 30, 2018.⁴ Compared to the TPP, the CPTPP's IP provisions are more comprehensive but with less scope. This paper provides a brief analysis of the suspended provisions and an overview of some notable changes the CPTPP brings.

The CUSMA replaces NAFTA. It will come into force in the second half of 2019.

Taken together, CETA, the CPTPP and the CUSMA have significant implications for patent protection, trademark and geographical indications, and copyright in Canada.

Patents

The key issues in the negotiations on patent protection are patentable subject matter, patent term extension, patent linkages and the right to appeal, and data exclusivity. The CETA provisions on patents apply exclusively to pharmaceutical products, while the patent provisions in the CPTPP and CUSMA are more general.

Patentable Subject Matter

Patentable subject matter is covered in CPTPP article 18.37 and USMCA article 20.F.1. It is not addressed in CETA.

The CUSMA standards are the most far-reaching in this respect and go beyond the CPTPP and NAFTA. CUSMA's article 20.F.1 requires that “patents are available for inventions claimed

1 See, for example, Maskus and Penubarti (1995); Maskus (2000); Rafiquzzaman (2002); Branstetter, Fisman and Foley (2006); Ivus (2010); Delgado, Kyle and McGahan (2013); Ivus (2015); Saggi (2016); Chen (2017); Ivus, Lai and Sichelman (2017); Ivus, Park and Saggi (2017).

2 See www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/index.aspx?lang=eng.

3 A list of suspended provisions can be found at: www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptppg/annex2-annexe2.aspx?lang=eng.

4 The date of December 30, 2018, is 60 days after October 31, when the sixth nation (Australia) ratified the agreement. Canada, Japan, Mexico, New Zealand and Singapore ratified the CPTPP before October 31.

as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product.”⁵ No comparable provision was included in NAFTA. It is in the original text of the TPP but is suspended under the CPTPP. Whether member nations should be required to include new uses, new methods of using or new processes of using existing products within the scope of patentable subject matter has been a controversial item in international trade talks. Proponents argue that this provision aims to encourage incremental or follow-on innovation, but it has been criticized for weakening patentability standards. Its application to pharmaceutical products has been particularly contentious. The provision serves to ensure that patent protection is available for new pharmaceutical products that build on previously discovered compounds. The main criticism is that such protection allows for “evergreening” of pharmaceutical patents by varying the originally patented compound only slightly and acquiring fresh patent rights for the new compound.

More generally, both the CUSMA and the CPTPP require patentability for “any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.”⁶ It is interesting that neither CPTPP article 18.37 nor CUSMA article 20.F.1 contains specific exclusions for computer programs and methods of doing business. In recent years, it has become difficult to obtain patent protection on certain software-related inventions in Canada and the United States. In Canada, for example, a computer program per se is excluded from patenting, but computer-implemented or computer-related inventions are patentable; and the actual boundaries of what constitutes patentable subject matter are not clear. For example, the Canadian Intellectual Property Office (CIPO) initially rejected Amazon’s patent application for its “1-Click” computer-implemented method on several grounds related to patentable subject matter (for example, that Amazon’s claims were for business methods, which are excluded from patentability under the Patent Act). However, following the decision

of Canada’s Federal Court of Appeal, the CIPO reconsidered its decision and granted the patent. By contrast, European patent law explicitly excludes computer-related inventions or business methods from patent protection, although the application of these exclusions is complicated. In order for a software or a business method invention to be patentable at the European Patent Office, the claimed invention must contain at least one novel feature that is “technical” and that solves a “technical problem” in a non-obvious manner.

Patent Term Extension

The patent term extension provisions serve to extend the effective term of a patent. Under the TRIPS Agreement, a patent expires 20 years after the initial filing date, but the effective term may be curtailed by initial delays by the patent-granting authority or regulatory approval processes. This loss of time is addressed in two ways. The first is the patent term adjustment (PTA) clause, which provides that unreasonable delays by a granting authority should not count against the patent’s term. The second is patent term restoration (PTR), which provides the same relief but specifically for delays in the “marketing authorization” of a pharmaceutical product.

CETA describes patent term extension as *sui generis* protection (i.e., in a class by itself). The period of *sui generis* protection is “equal to the period which elapsed between the date on which the application for the basic patent was filed and the date of the first marketing authorisation, reduced by a period of five years.”⁷ In other words, the patent term of a new pharmaceutical product would be extended if the patent-granting and regulatory approval process delays the entry of the product into the market by more than five years. CETA stipulates that “the duration of the *sui generis* protection may not exceed a period of two to five years, to be established by each Party.”⁸ At the time of CETA negotiations, Canada did not provide any form of PTR to address lost marketing opportunities in situations of delayed regulatory approvals. But under CETA, Canada has agreed to provide up to two years of *sui generis* protection for eligible

5 CUSMA, art. 20.F.1, https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20_Intellectual_Property_Rights.pdf.

6 CPTPP, art. 18.37(1), <https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/18.aspx?lang=eng>; CUSMA, art. 20.F.1(1), emphasis added.

7 CETA, art. 20.27(5), www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng.

8 *Ibid.*, art. 20.27(6).

pharmaceutical patents. In the European Union, the period of *sui generis* protection is five years.⁹

CUSMA (article 20.F.9) stipulates PTA for unreasonable granting authority delays, defined as “a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later.” It does not specify a minimum period of PTA and, instead, requires each Party “to provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for such delays.”¹⁰ The agreement (article 20.F.11) also provides for PTA for unreasonable curtailment due to delays in marketing approval of a pharmaceutical product, but here it also does not specify a minimum adjustment period and instead stipulates “compensation.”

The language of the PTA provisions in the TPP is similar to that in the CUSMA, but the CPTPP sets out important changes to these provisions. The CPTPP suspends the provision on PTA for unreasonable granting authority delays (TPP article 18.46) and also the provision on PTR for unreasonable curtailment of the effective patent term as a result of the marketing approval of a pharmaceutical product (TPP article 18.48).¹¹

Patent Linkages and the Right to Appeal

Patent linkage is a mechanism linking the marketing approval of a generic pharmaceutical product to the status of the patent(s) corresponding to its branded equivalent. This system aims to promote the resolution of pharmaceutical patent disputes.

In Canada, the Patented Medicines (Notice of Compliance) (PM[NOC]) Regulations link the patent regime to regulatory approval by Health Canada. The pharmaceutical innovator who filed a new drug submission could include its related patents with

the submission to the Patent Register maintained by Health Canada. This provides a “patent linkage” mechanism. Any supplier wishing to introduce a generic version of a name brand drug into the market has to certify that its generic product does not infringe the original or linked patents in the Patent Register or that the original patents are invalid, in order to justify the issuance of an NOC. If the pharmaceutical innovator believes that its patents are infringed upon, it could ask the Federal Court to prevent Health Canada from issuing the requisite NOC. Under the previous regulations, if the pharmaceutical innovator lost the case and Health Canada issued the NOC, the generic product entered the market immediately and any appeal by the innovator was rendered moot. The innovators’ recourse was to initiate an infringement action under the Patent Act. This led to duplicative litigation over the same patent, with potentially inconsistent outcomes, and invited complaints that the system was unfair and unpredictable.

CETA’s article 20.28 sets out that “if a Party relies on ‘patent linkage’ mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal.” Canada’s commitment under CETA gives scope for Canada to give the pharmaceutical innovators an effective right of appeal and end the practice of duplicative legal proceedings.

Canada is also required to provide a form of patent linkage for pharmaceutical products under the CPTPP’s article 18.53 and the CUSMA’s article 20.F.16, the text of which is identical. These provisions require each party to provide: a system to notify a patent holder that someone is seeking to market a generic version of a previously approved pharmaceutical product, claiming the approved product or its approved method of use; procedures and expeditious remedies (for example, preliminary injunctions) to enable the resolution of disputes concerning the validity or infringement of an applicable patent; and adequate time and opportunity for such a patent holder to seek available remedies, prior to the marketing of an allegedly infringing product.

9 In addition to capping the term of *sui generis* protection, CETA provides that only a single period of *sui generis* protection would be available, regardless of whether a product is protected by one or more than one patent that may serve as a basic patent; the *sui generis* protection would take effect at the end of the lawful term of the basic patent.

10 CUSMA, art. 20.F.9(4), https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20_Intellectual_Property_Rights.pdf.

11 CPTPP, art. 18.48, <https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-tpf/text-texte/18.aspx?lang=eng>.

Data Exclusivity

Data exclusivity refers to the protection of property rights in pharmaceutical registration data, which is preclinical and clinical trial data that a pharmaceutical innovator company must submit to regulators to establish the efficacy and safety of its new pharmaceutical product. During the period of data exclusivity, a manufacturer of a generic drug or a biosimilar product is prevented from referencing (comparing to) the registration data in its own regulatory filing for the same drug substance. The duration of data exclusivity is not added to the patent life. The data exclusivity provisions aim to impose regulatory barriers to make it harder for generic drug makers to piggyback on innovators' data, and, in return, making it easier for pharmaceutical innovators to recoup their drug development and clinical trial expenses.

The period of data exclusivity varies between countries. In the European Union, the cumulative period of data exclusivity is 10 years, which includes eight years of data exclusivity and two years of market exclusivity. In the United States, further distinction arises between traditional small molecule drugs and biologic drugs, which are or contain a biologic derived from genetic material, cells or other biological sources using biotechnology; the period of data exclusivity is five years for traditional small molecule drugs and 12 years for biologics. Canada currently provides eight years of exclusivity for an innovator pharmaceutical product, biologics or traditional small-molecule drugs alike. A manufacturer of a biosimilar or generic drug cannot reference an innovator drug for six years from the date of the innovator drug's first marketing authorization and cannot obtain marketing authorization for an additional two years.

CETA's article 20.30 provides eight years of protection for undisclosed data related to pharmaceutical products. More precisely, it provides for six years of data exclusivity but also prevents a party from granting an authorization to a generic manufacturer that relies on the innovator drug's registration data for at least eight years from the date of the first marketing authorization of the drug. This provision is in line with Canada's current practice. Canada did not meet the European Union's request to extend its period of data exclusivity to 10 years, which would have aligned its practice with that of the European Union.

The CUSMA prohibits generic drug manufacturers from marketing the same or similar product based on the registration data without the consent of the innovator firm for at least five years from the date of marketing approval (article 20.F.13). For biologics, the CUSMA provides eight years of data exclusivity (article 20.F.14).

The CPTPP suspends the original TPP articles 18.50 and 18.51, which provided five years of data exclusivity for traditional small molecule drugs and eight years of data exclusivity for biologics, respectively. But the CPTPP retains article 18.47, which requires 10 years of data exclusivity for a new agricultural chemical product.

Trademark and Geographical Indications

Geographical indications (GIs) are used to designate goods from a particular geographical origin. CETA includes protections for a number of EU GIs in Canada; in order to comply with its obligations under CETA, Canada amended the Trade-marks Act accordingly. The amendments expand the definition of GI (which previously included only wines and spirits) to include agricultural products and foods, such as certain cheeses, meats, baked goods, oils, spices, nuts, cereals and animal fats.

CPTPP section C governs trademark protection and section E governs GIs. These sections are adopted in full (without modifications) from the original TPP agreement. Under the new rules, trademark registration would no longer be restricted to "visually perceptible" signs, and the grounds for denying registration would be more limited.¹² The CPTPP expands trademark protection to certification marks, which are imprimaturs used to designate goods as certified by a specific collective or originating from a specific association.¹³ So too with GIs.¹⁴ The CPTPP expands the scope of "well-known trademarks" by eliminating some of the conditions used to establish "well-known" status¹⁵ and by removing the condition, originating in the Paris Convention, obtaining

¹² *Ibid.*, art. 18.18.

¹³ *Ibid.*, art. 18.19.

¹⁴ *Ibid.*, art. 18.30.

¹⁵ *Ibid.*, art. 18.22(1).

well-known status in a member country required the trademark to be well known in that country.¹⁶

The text of the USMCA's trademark and GI provisions is essentially identical to the text of the CPTPP's sections C and E.

Copyright

Under current Canadian law, the term of copyright protection for works, performances or phonograms is the creator's life plus 50 years.

The CUSMA obliges Canada to extend the term of copyright protection to the creator's life plus 70 years. This provision was also in the original TPP text (article 18.63) but is suspended in the CPTPP. The CUSMA's article 20.J.11 also obliges each party to ensure that legal remedies are available for right holders to address copyright infringement and include "safe harbour" provisions that protect ISPs from liability for copyright infringement that occurs on their networks. In particular, the CUSMA requires each party to enable a copyright owner that has made a legally sufficient claim of copyright infringement to obtain from an ISP information in the provider's possession identifying the alleged infringer. The CPTPP, on the other hand, suspends the TPP's "Legal Remedies and Safe Harbours" provision (article 18.82), which is essentially identical to the CUSMA's article 20.J.11.

The CUSMA provides legal protection and remedies against the circumvention of technological protection measures (TPMs), which are "digital locks" that copyright owners employ to prevent or control access to copyright content.¹⁷ It also provides legal remedies to protect rights management information (RMI) on copyrighted works, which are "digital watermarks" that identify rights related to that work (for example, copyright notices, publishers' information and permissions). Such information is typically used with documents, and it might prevent users from making legitimate, non-commercial modifications to the goods they purchase. These CUSMA provisions criminalize the circumvention of TPMs and removal or alteration of RMI when performed wilfully and for the purposes of commercial advantage or financial gain. By contrast, the CPTPP suspends the corresponding TPP provisions (articles 18.68

and 18.69). However, Canada's Copyright Act is largely already in compliance with the TPMs and RMI provisions of the CUSMA. For example, digital rights management schemes (DRMs) are protected under existing Canadian law prohibiting the circumvention of DRMs or marketing of products or services that would do the same.

Nature and Scope of IP Obligations under Trade Agreements

Existing Agreements

The IP provisions in CETA, the CPTPP and CUSMA are meant to coexist with the existing international IP-related agreements, and they are best understood as affirming or extending existing IP rights.

The IP provisions in CETA complement the rights and obligations between the parties under the TRIPS Agreement. All CETA parties must also comply with the international agreements related to copyright — for example, the Berne Convention for the Protection of Literary and Artistic Works, the World Intellectual Property Organization (WIPO) Copyright Treaty, the WIPO Performances and Phonograms Treaty — and must make all reasonable efforts to comply with other international agreements related to trademarks, industrial designs and patents.¹⁸

All CPTPP signatories must have ratified or acceded to the Patent Cooperation Treaty, the Paris Convention (covering industrial IP), the Berne Convention for the Protection of Literary and Artistic Works, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty prior to the March 2018 signing, as well as several other IP-related agreements prior to the CPTPP coming into force.¹⁹

¹⁶ *Ibid.*, art. 18.22(2).

¹⁷ CUSMA, art. 20.H.11.

¹⁸ CETA, art. 20.7, 20.13, 20.24, 20.26, www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng.

¹⁹ CPTPP, art. 18.7.

Also, each party to the CUSMA must have ratified or acceded to the Patent Cooperation Treaty, the Paris Convention, the Berne Convention for the Protection of Literary and Artistic Works, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty, and other IP-related agreements by the date of entry of the CUSMA into force.²⁰

How Do IP Provisions in CETA, the CPTPP and the CUSMA Fit within the Canadian Legal Framework?

Changes to IP protection under CETA, the CPTPP and the CUSMA aim to bring Canada's IPR regime more in line with the regimes of other countries. These agreements establish certain minimum standards of IPR protection that all parties must provide. The minimum standards have often been characterized as a harmonization of IPR protection across countries; however, the two are not the same. The CUSMA, for example, requires all members to offer copyright protection for at least 70 years, but countries are free to offer copyrights of longer duration. Article 20 of the CUSMA, for example, clarifies that "a Party may, but shall not be obliged to, provide more extensive protection for, or enforcement of, intellectual property rights under its law than is required by this Chapter." Also, while the IP provisions in international trade agreements oblige member countries to make important changes to their IPR regime, the agreements leave it up to the member countries to decide how to implement the provisions. CETA, the CPTPP and the CUSMA, in particular, set out that "each Party shall be free to determine the appropriate method of implementing the provisions... within its own legal system and practice."²¹

In order to implement CETA, Canada is required to make important changes to several federal acts, including the Patent Act and the Trade-marks Act. The Canada-European Union CETA Implementation Act, which came into force on September 21, 2017, includes a number of IP law provisions that improve the consistency of IP laws and regulations between Canada and the European Union. The most notable changes concern patent protection in the pharmaceutical and biologics industries.

Specifically, the Patent Act has been amended by adding a Supplementary Protection Certificate (SPC) system similar to the European SPC system. Thus, Canada now provides a *sui generis* form of patent term restoration. The Certificates of Supplemental Protection (CSP) are capped at two years. The CSP protection is limited to patents that pertain to a "medicinal ingredient, or combination of medicinal ingredients," does not extend to multiple patents (only one patent can be eligible) and does not extend to exports. The act also amended the PM(NOC) Regulations to revise the process by which patent infringement and validity disputes under the PM(NOC) Regulations are resolved. The revisions address the concerns that both innovators and generics had with the previous system (i.e., the inability of pharmaceutical innovators to appeal and the legal uncertainty for generic manufacturers that dual litigation over the same patent entails).

Why Include IP Provisions in Trade Agreements?

The Rationale for International Coordination of IPRs

In a classic analysis, William D. Nordhaus (1969) derived the optimal patent length of a single economy in isolation. The benefit of IP protection is that it provides creators with an incentive to innovate and introduce socially valuable inventions that otherwise would not have been found. A patent gives its holder a statutory right to exclude others from making, using, selling or importing the patented invention for a specific period. This right of exclusion, in turn, allows the patent holder to earn a monopolistic return on the cost of their creation and derive the material reward for their intellectual effort and research leading to the invention. The cost of IP protection is that it raises the price of protected products above market levels and limits the access to innovative products and technologies.

In light of these arguments, the optimal level of IP protection would appear to be some middle ground that strikes a balance between providing sufficient incentive to create and innovate while limiting the social cost of insufficient access to these new creations and innovations. Nordhaus (1969)

20 CUSMA, art. 20.A.7.

21 CETA, art. 20.2; CPTPP, art. 18.5; CUSMA, art. 20.A.5.

showed that the optimal patent length balances these benefits and costs at the margin, where the marginal benefit depends on the elasticity of innovation with respect to patent protection; and the additional consumer surplus generated by newly invented products and the marginal cost depends on the total consumer surplus foregone by prolonging a monopolistic market structure.

The above analysis remains highly applicable today, but it ignores one key consideration: the globalization of IP. Modern economies are largely interlinked, and one country's regime of IPRs may influence other countries' policies. Lawmakers must take into account this global interdependence. The key question in this respect is: do the incentives for patent protection of a trading world economy differ from those in a closed economy?

In a trading world economy, IPRs are no longer just a way to foster domestic innovation. They also become a strategic instrument to affect global income distribution among nations. This is the key insight of Gene M. Grossman and Edwin L.-C. Lai (2004). The authors studied the strategic interactions between countries in the setting of their patent policies. The analysis showed that the incentives a government has for protecting IP in a trading world economy are weaker compared to those in a closed economy without international trade. This is for two reasons. First, the static cost of monopolistic pricing is higher in an open economy because the profits that patent holders earn in the foreign market do not enter into a government's calculation. Second, the dynamic benefit of increased innovation is lower in an open economy. Domestic innovation in an open economy is less responsive to national patent policy because domestic innovators earn only a fraction of their profits in the domestic market, with the remainder earned in foreign markets and dependent on foreign patent protection. Consequently, the government's ability to stimulate innovation with an enhanced protection of IP is lower for an open economy. The analysis further shows that patent protection tends to be stronger in a larger market because it has greater impact on global innovation, and that the complete harmonization of patent policies around the world is neither necessary nor sufficient for achieving global efficiency.

Limitations and Flexibilities in the IP System

IP provisions in international trade agreements limit the freedom to use IP policy to promote national interests, but the various IP obligations are also counterbalanced by several flexibilities, including the right to establish local exhaustion policies.

National Treatment and Most Favoured Nation Treatment

IP-related RTAs often explicitly include two fundamental provisions: national treatment and most favoured nation treatment (MFN). These provisions are the two non-discrimination principles of the multilateral trading system. They were declared in the General Agreement on Tariffs and Trade (GATT), the precursor to the World Trade Organization (WTO), and are recognized in the TRIPS Agreement. The rule of national treatment is also the fundamental principle in the Paris Convention, the Berne Convention, the Rome Convention and other international IP conventions in force prior to the TRIPS Agreement. The MNF rule, by contrast, is new to international IP relations; the TRIPS Agreement is the first agreement to recognize it.

National treatment is a principle of giving others the same treatment as one's own nationals. In the context of trade-related IPRs, this principle prohibits discrimination between imported and domestically produced goods with respect to the protection of IPRs, which includes matters related to availability, acquisition, scope, maintenance and enforcement of IPRs. Article 18.8(1) of the CPTPP, for example, states: "In respect of all categories of intellectual property covered in this Chapter, each Party shall accord to nationals of another Party treatment no less favourable than it accords to its own nationals with regard to the protection of intellectual property rights."²² This implies that as with every other party, Canada is forbidden from promoting homegrown IP with more favourable or streamlined treatment to Canadian registrants.

²² The CPTPP suspends the original TPP provision on national treatment dealing with payment on copyright and related rights.

The MFN obligation is stated in article 4 of the TRIPS Agreement, which provides that “with regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.” Importantly, the TRIPS MFN provision lacks any exceptions allowing discriminatory privileges to RTAs (Reichman et al., 2016). Pursuant to the TRIPS Agreement, any WTO member that grants expanded IPRs to one or more countries is deemed to grant the expanded rights to all WTO member countries. This is critical, as over the past decades, a large increase in the number of trade agreements that included IP-clauses has been observed (Maskus and Ridley 2016). Under the CUSMA, for example, Canada is obliged to extend the term of copyright protection to the creator’s life plus 70 years, which is above the 50-year minimum required by the TRIPS Agreement. The MFN principle implies that such TRIPS-plus provisions are spread beyond the agreements’ members and serve to ensure that IPRs and protections only grow stronger across the globe (Maskus 2012). Whether this is desirable from an economic perspective is an open question at this point (Ivus and Saggi 2018).

Flexibilities

The various IP obligations under the TRIPS Agreement are counterbalanced by several major flexibilities. On such flexibility is the right to establish local exhaustion policies. In IP law, the exhaustion doctrine (also known as the “first-sale” doctrine) represents a limit on IPRs. In the context of patents, the doctrine holds that upon the initial authorized sale of a patented item, the patent rights in that item are exhausted, precluding later claims of patent infringement against subsequent purchasers. In some cases, the doctrine has been held to apply only nationally (i.e., to sales within a country), while other cases have applied the doctrine internationally (i.e., to sales anywhere in the world). The TRIPS Agreement assigns jurisdiction over the matter to individual members; article 6 states: “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”²³ Likewise, CETA’s article 20.4 states: “This Chapter does not affect the freedom of the Parties to

determine whether and under what conditions the exhaustion of intellectual property rights applies.”²⁴

In Canada, the doctrine of exhaustion has not received much attention. The term patent exhaustion is not used in Canadian statutes or case law, and there are no express provisions in the Patent Act or Trade-marks Act akin to the doctrine. Likewise, there is no binding court decision establishing that an initial authorized sale of a patented item “exhausts” all rights of the patentee to that item under Canada’s Patent Act. Instead, the Canadian courts rely on the doctrine of implied licence and the notion that an unconditional purchase of a patented item grants an implied licence to the purchaser to deal with the item without restriction. The Supreme Court of Canada’s judgment in *Eli Lilly and Co v Apotex Inc* (1998) effectively presumes exhaustion while permitting patent owners to expressly reserve their rights.²⁵ Were a purchaser to violate those express restrictions, it would be liable for patent infringement and the patent holder would have remedies in patent law. At the same time, the treatment in *Monsanto Canada Inc v Schmeiser* (2004) does not recognize the exhaustion doctrine and is viewed as a rejection of the existence of the patent exhaustion doctrine in Canada (de Beer and Tomkowicz 2009).

The shaping of the patent exhaustion policy has potentially large implications for the production and pricing decisions of innovative firms, and it is within the remit of the Government of Canada. Olena Ivus (2018) argues that Canadian courts should be more upfront in dealing with issues concerning patent exhaustion and the public policy goals the doctrine serves. If Canada applies the doctrine internationally, it would encourage firms outside Canada to create parallel distribution channels for re-importing patented products into Canada without the authorization of Canadian patent holders. Such incentives are strong in low-price markets, where prices are below Canada’s level. However, opportunities

23 See www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm.

24 See www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng.

25 Although not explicit, the court established that the authorized sale of a patented item “exhausts” the patent rights in the item sold, unless those rights are expressly reserved by contract and communicated to purchasers. This treatment allows the patent owner to opt out of exhaustion via express contractual restrictions or, more precisely, to rely on express restrictions to override the implicit right or licence to use or resell the item.

for arbitrage are typically short-lived. In order to prevent arbitrage, patent holders increase prices for patented products in low-price markets and reduce them in high-price markets. This would imply lower prices for consumers in Canada.

The regime of international patent exhaustion in Canada would also increase certainty over the “price” of patented goods for patent users. This is particularly so in complex technology sectors, where it is often difficult for patent users to trace the patent rights of every component (i.e., determine which components are within the scope of a valid and enforceable patent, whether the patentee has reserved the patent rights and whether a component completely practices or embodies the patent in suit). The increased certainty would reduce the costs of using patented components in further innovation- or commercialization-related activities by downstream entities and lower the transaction cost of gathering the required information and obtaining the legal rights when necessary. This, in turn, would spur business activity in Canada and encourage cross-border sourcing of patented intermediate components and their use in global production. On the other hand, stronger IP protection in the form of national exhaustion would increase the patent holders’ profit and in doing so, might increase the amount of *ex ante* innovation that the patent owner is willing to make. In general, the benefits of exhaustion will depend on unique industry and technology structures (Ivus and Lai 2017; Ivus, Lai and Sichelman 2017).

Discussion and Recommendations

The inclusion of protections for innovators’ profits and technologies in the form of IPRs is fiercely promoted by the United States and the European Union, almost as fiercely as it is resisted by countries with smaller stocks of IP. An important source of the conflict had to do with how the two sides view the likely impact of strengthening IPR protection around the world on international technology transfer and global innovation. The transfer of technology is an express objective of the TRIPS Agreement. The CPTPP’s chapter 18 also

states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”²⁶ Similarly, the stated objectives of CETA’s chapter 20 are to “a. facilitate the production and commercialisation of innovative and creative products, and the provision of services, between the Parties; and b. achieve an adequate and effective level of protection and enforcement of intellectual property rights.”²⁷ If achieved, increased technology transfer would be viewed as just compensation by countries with smaller stocks of IP in return for making their IP regimes compliant with IP provisions in international trade agreements. However, this outcome is hardly guaranteed. Critically, there is ample evidence on the importance of the “absorptive capacities” of a given country in influencing the impacts of stronger IPRs. The positive impact of stronger IPRs on innovation is often conditional on the initial innovative activity levels in the industry or the supply of skilled workers. Countries with an insufficient scale of innovation-intensive industries will not be able to benefit from stronger IPRs.

In addition to country characteristics, the effects will also differ by type of sector. Alberto Galasso and Mark Schankerman (2014), for example, show that in sectors with cumulative research (such as computers, electronics and medical instruments), strong patent rights block downstream innovation. Invalidation of patents owned by large patentees renders follow-on innovation less costly and triggers more follow-on innovation by small firms.

The international competitiveness of domestic firms is also affected by the costs of IP protection within a national legal framework. In this respect, Canada should consider overhauling some of its regulatory processes that pose barriers to innovation. Reducing the costs of IP protection would better position homegrown innovating firms to compete globally. Given that under the principles of national treatment and MFN,

26 CPTPP, chap. 18, art. 18.2.

27 CETA, sec. A, art. 20.1, www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng.

Canada cannot promote homegrown IP with more favourable or streamlined treatment to Canadian registrants, reducing costs for Canadians might be achieved through tax credits or grants.

Canada's use of national IP policy is limited by international IP systems and IP-related international trade agreements. Nonetheless, the Canadian government will continue to enjoy some discretion in establishing national IPR policy and enforcing the new rules. While respecting the limits, Canada should exercise that discretion in the best interests of Canadian stakeholders.

The scope of IP policy is very broad, ranging from issues related to patenting to trademarks and GIs. This is further complicated by the coexistence of the areas controlled by the multilateral rules and MFN clause and the areas within the national jurisdiction, for example, exhaustion policy. While the multilateral IPR reforms, as triggered by the trade agreements, have attracted a fair amount of academic attention, the role of the national policy has been relatively under-researched. Both academics and policy makers would benefit from more evidence on the importance of national IP policy and its intersection with multilaterally regulated IPRs.

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67 Erb Street West
Waterloo, ON, Canada N2L 6C2
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